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9  
10 **IN THE UNITED STATES DISTRICT COURT**  
11 **FOR THE DISTRICT OF ARIZONA**

12 **IN RE: Bard IVC Filters Products**  
13 **Liability Litigation**

No. MD-15-02641-PHX-DGC

(Oral Argument Requested)

14 **PLAINTIFF'S RESPONSE TO**  
15 **DEFENDANTS' MOTION *IN LIMINE***  
16 **NO. 1 TO EXCLUDE EVIDENCE OF**  
17 **RECOVERY FILTER CEPHALAD**  
18 **MIGRATION DEATHS**

19 (Assigned to the Honorable David G.  
20 Campbell)

21 (Tinlin Bellwether Case)  
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**I. Recovery Filter Deaths Involving Migration are Relevant and Admissible.**

Evidence of Recovery Filter migration deaths is admissible as it involves the same defects, involves similar circumstances, and is a critical component of demonstrating the magnitude of risk that the Recovery Filter actually posed to implanted patients and lack of substantial similarity with its predicate device. This evidence also demonstrates Bard's knowledge of the seriousness of Recovery failures and concealment of these risks.

Whether incidents are substantially similar for admissibility purposes depends on the theory of the case. *Younan v. Rolls-Royce Corp.*, 2013 WL1899919, at \*9 (S.D. Cal. May 7, 2013) (substantial similarity requirement relaxed when used for notice) (quoting *Four Corners Helicopters, Inc. v. Turbomeca, S.A.*, 979 F.2d 1434, 1440 (10th Cir. 1992)). Dissimilarities that are minor or immaterial do not prevent admission of evidence. *White v. Ford Motor Co.*, 312 F.3d 998, 1009 (9th Cir. 2002) (citing *Cooper v. Firestone Tire & Rubber Co.*, 945 F.2d 1103, 1105 (9th Cir. 1991) (evidence of dissimilar accidents admissible to impeach claim that product is "generally safe" even though incident would be excluded if used to prove negligence, design defect, or notice)). "If products share the specific design features alleged to be defective, it may be that other differences between the products, such as tire size, are 'immaterial'." *Albee v. Cont'l Tire N. Am., Inc.*, 2010 WL 1729092, at \*6 (E.D. Cal. Apr. 27, 2010) (quoting *White*, 312 F.3d at 1009).

Courts have routinely denied motions *in limine* seeking to exclude evidence of adverse event reports and similar evidence. *See, e.g., Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000) (holding proper to admit 270 complaints relating to defendant's silicone gel breast implants to establish notice that product was fragile). Because the Recovery death evidence involves the same model and failures that stem from the same flawed design, this evidence should be admitted.

Bard's attempt to differentiate cephalad migration from the migration and other failures that injured Mrs. Tinlin is a distinction without a difference. Bard analyzed all filter failures while tracking and trending these adverse events at the time the Recovery Filter

1 was on the market. *See* Exhibit A, [Trial Exhibit 927], p. 4 (aggregating severity and  
 2 likelihood of death, migration, fracture, etc., to calculate total rate of serious injury). It is  
 3 disingenuous for Bard to now decide which migrations it deems relevant when all failures  
 4 were relevant for purposes of evaluating the safety of its product.

5 Notwithstanding that Mrs. Tinlin did experience a migration, it is also implausible  
 6 to suggest that the parties can refer to testimony by Bard's witnesses addressing risk,  
 7 seriousness, and lack of substantial equivalence without also referencing underlying deaths.  
 8 All of the evidence of Bard's investigations and decision-making concerning Recovery  
 9 Filter migrations relate to or reference a death or deaths, as well as rely on the facts relating  
 10 to these deaths (including frequency and severity). As such, there is no realistic way to  
 11 separate out the migration-death references from the whole of Bard's activities – they were  
 12 the basis for those actions.<sup>1</sup> For example, although there is testimony regarding Bard's  
 13 investigation into Recovery-related deaths, none of that testimony relates to any  
 14 investigations into or root cause analysis of cephalad migration independent of the deaths.  
 15 *See, e.g.*, Exhibit B, Deposition of Len DeCant dated May 24, 2016, at 263:6-264:9.

16 Finally, any issues of reliability or bias go to the weight of the evidence. Bard is free  
 17 to offer testimony or other evidence regarding any deficiencies it perceives in the reports  
 18 but the probative value is not substantially outweighed by undue prejudice.

## 19 **II. The Court should apply its Reasoning from *Booker*.**

20 Bard argues in its motion *in limine* that this Court should overlook its order from  
 21 *Booker* and instead apply the analysis used in the *Hyde* and *Jones* cases. But doing so is  
 22 illogical. This case involves a Recovery Filter, which is the same filter involved in the very

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23 <sup>1</sup> Bard's count of trial references to filter models is disingenuous, first because in *Hyde*  
 24 there was a dispute about the filter at issue (combined, "Eclipse and G2x" were mentioned  
 25 approximately 1,200 times); second, because Bard neglected show which party referenced  
 26 these terms and failed to tell the Court how many times the closely-related G2 filter was  
 27 mentioned (more than 1,000 in *Hyde*, based on counsel's unscientific query of the  
 28 transcript); and, finally, because Bard has not demonstrated any relevance of these counts  
 to the evidence at issue here. To the contrary, the experience from the past three  
 bellwether trials demonstrates the difficulty in presenting evidence to the jury without  
 referencing migration deaths. Eliminating these references created evidence that does not  
 actually exist (for example, the jury in the *Jones* and *Hyde* cases was left with the false  
 impression that Bard implemented a "product hold" based only on migrations).

1 evidence Bard seeks to exclude. *Booker* involved a G2 filter, the next generation filter after  
2 the Recovery filter. In *Booker*, this Court held that the Recovery Filter's failures were  
3 "substantially similar" to the alleged G2 filter's failures, and therefore the evidence was  
4 admissible, stating "the Court concludes that known complications with the Recovery filter  
5 are plainly relevant to this case." See Order, Doc. 10528, Sec. A. This Court excluded this  
6 evidence in *Hyde* or *Jones* because those cases involved later generation filters and thus the  
7 Recovery evidence was deemed to be less relevant.

8 **III. Recovery Death Evidence Is Relevant to Plaintiff's Failure to Warn and**  
9 **Punitive Damages Claims.**

10 When balancing the risks and benefits of a medical device, a physician must consider  
11 both the frequency and severity of a device failure to make an informed decision, which  
12 must then be communicated to the patient for there to be proper informed consent. Bard  
13 should have warned Plaintiff's implanting physician about the overall risk profile of the  
14 Recovery Filter which includes the risk of catastrophic failure and death. Bard's  
15 concealment of the true risk profile associated with the Recovery Filter directly impacted  
16 the risk/benefit analysis and is therefore relevant and admissible in this case.

17 **IV. Admission of Migration Death Evidence Will Not Violate Due Process.**

18 Due process concerns arise where a defendant is punished for acts that did not result  
19 in harm to the plaintiffs in a particular case. That concern does not arise here. The evidence  
20 at issue tends to show that Bard knew of and concealed severe risks of its filters from doctors  
21 and patients, knowing, and consciously disregarding that severe injury was substantially  
22 certain to result. Migration death evidence is thus evidence that caused or contributed to  
23 Mrs. Tinlin's injury, unlike in the cases cited by Bard. *Henrikson v. Strapon*, 758 N.W.2d  
24 205, 211 (Wis. 2008) (no evidence conduct caused or contributed to injury); *Kehl v.*  
25 *Economy Fire & Cas. Co.*, 433 N.W.2d 279, 280 (Wis. Ct. App. 1988) (same).

26 For the foregoing reasons, Plaintiff respectfully requests that Bard's motion *in*  
27 *limine* to exclude evidence of Recovery Filter cephalad migration deaths be denied.  
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2 RESPECTFULLY SUBMITTED this 12<sup>th</sup> day of April, 2019.

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 12th day of April, 2019, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine